Specifications and Certificate of Analysis

Lipomed Document QC-CA-663
Version 003-12.Sep.2008 Supersedes: 002-26.Sep.2006

Chemical name: **Ketamine.HCl**

CAS Registry Nr: 1867-66-9

Chemical formula: $C_{13}H_{16}ClNO$-Hydrochloride Molwt: 237.73 / 274.19

Lot No: 663.1B0.1
Art. Nr. KET-663-HC

Retested: 26.09.2023
Retest date: **September 2026**

TEST	SPECIFICATIONS	RESULTS
1. Appearance	white to off-white crystalline powder	conforms
2. Identity	IR	IR corresponds
	UV: in methanol $\lambda_{max,1}$ = 269.0 ± 1.0 nm $\varepsilon_{mol,1}$ = 600 ± 100 $\lambda_{max,2}$ = 276.0 ± 1.0 nm $\varepsilon_{mol,2}$ = 500 ± 100	UV: in methanol $\lambda_{max,1}$ = 269.0 nm $\varepsilon_{mol,1}$ = 590 $\lambda_{max,2}$ = 276.1 nm $\varepsilon_{mol,2}$ = 514
3. Melting point: 261 ± 3 °C (dec)		259.2 – 260.9 °C (dec)
4. Purity The purity is calculated from the distribution of 6 HPLC analyses with a 95% level of confidence.	HPLC > 98.5 %	99.248 ± 0.105 %
5.Optical rotation	N/A (racemic mixture)	N/A
6.Free base content (Corrected from purity and water)	> 84.4 %	85.9 %
7. Water content	Karl Fischer < 1 %	0.16 %
8. Calculated hydrochloride content		13.3 %

FOR ANALYTICAL PURPOSES ONLY: NOT FOR HUMAN USE!

The material should be stored at +2 to +8 °C in a dry and cool area in a closed container. Lipomed certifies that the identity and chemical purity of this reference standard is based on exhaustive analytical tests. Gravimetric preparation of this bulk standard is ensured by using balances calibrated with ilac-MRA traceable weights.

QC - Officer: Deputy: Dr. L. Prévot

Date sign: Arlesheim,

September 27, 2023

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